

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Fenical et al.
App. No : 10/561,711
Filed : September 11, 2009
For : SALINOSPORAMIDES AND
METHODS FOR USE THEREOF
Examiner : Powers, Fiona
Art Unit : 1626
Conf # : 1035

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF MICHAEL A. PALLADINO, JR., PH.D.
UNDER 37 C.F.R. 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Michael A. Palladino, Jr., Ph.D., declare and state as follows:

1. I am a Senior Vice President, Chief Technology Officer and Scientific Co-founder of Nereus Pharmaceuticals, Inc. Nereus Pharmaceuticals, Inc. is the licensee of the above-referenced patent application, U.S. Patent Application No. 10/561,711.

2. I received a B.S. degree in biology from St. Peters College in 1971, an M.S. in biochemistry from Farleigh Dickinson University in 1974, and a Ph.D. in pathology/immunology from New York University in 1978. I held postdoctoral positions at New York University and Memorial Sloan Kettering Cancer Center in New York. I worked as Director of Cell Biology and Director of Research Strategies at Genentech Inc. in South San Francisco, California. Additionally, prior to co-founding Nereus Pharmaceuticals, I served as vice president for Preclinical Development at IXSYS (now called Applied Molecular Evolution and purchased by Lilly) in San Diego. I have published over 250 scientific articles, have served as an associate

editor on multiple leading scientific journals, including Cancer Research and am an inventor on multiple issued patents in the areas of cancer and inflammation.

3. I have reviewed the March 9, 2011 Office Action in U.S. Application Serial No. 10/561,711. I also have reviewed the specification and the pending claims in this application. I am familiar with the specification, the pending claims, and the March 9, 2011 Office Action.

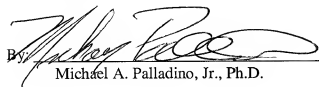
4. I understand that Claims 10-13 have been rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement. According to the March 9, 2011 Office Action at page 5, the "only direction or guidance present in the instant specification is data on page 31 for inhibition of colon cancer cells." Further, according to the March 9, 2011 Office Action at page 6, "the specification fails to provide sufficient support of the broad use of the compound of the instant claims in a method of treating the listed mammalian cell proliferative disorders and any cancer." Therefore, the March 9, 2011 Office Action states at page 7 that "one of skill in the art would have to engage in undue experimentation to test which diseases can be treated by the compound encompassed by the instant claims, with no assurance of success."

5. Respectfully, I disagree with the rejection of the claims because I believe that the claimed subject matter of Claims 10-13 is enabled. The purpose of this declaration is to provide data demonstrating that the claimed methods are enabled.

6. The specification describes that compounds encompassed by the claims are excellent candidates for use in the treatment of refractile (refractory) cancers. See paragraphs [0051]. Furthermore, the specification at paragraph [0062] describes methods of treating the following neoplasms: mamm[al]ary, small-cell lung, non-small-cell lung, colorectal, leukemia, melanoma, pancreatic adenocarcinoma, central nervous system (CNS), ovarian, prostate, sarcoma of soft tissue or bone, head and neck, gastric which includes thyroid and non-Hodgkin's disease, stomach, myeloma, bladder, renal, neuroendocrine which includes thyroid and non-Hodgkin's disease and Hodgkin's disease neoplasms.

7. The scientific and patent literature supports the enablement of the claimed subject matter. Appendix A provides a list of examples from the scientific and patent literature, of which I am familiar, that support my position that Claims 10-13 are enabled. A copy of each listed scientific or patent literature reference is submitted herewith in Appendix B.

8. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information or belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patent issued thereon.

By: 
Michael A. Palladino, Jr., Ph.D.

Date: 6/8/11